DEC 3 1 2003

K033671 P.1/3

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Proprietary Name:	GORE BIOABSORBABLE MESH
Common Name:	Bioabsorbable Mesh
Classification Name:	Mesh, surgical, polymeric
Device Classification:	Class II
Product Classification and Code:	878.3300, FTL
Classification Panel:	General and Plastic Surgery Devices
Establishment Registration Number:	2025240
Contact Person:	Brandon Hansen Regulatory Affairs Medical Products Division W. L. Gore & Associates, Inc. 3450 West Kiltie Lane Flagstaff, AZ 86002-0500 Telephone: (928) 864-3784 Facsimile: (928) 864-4144 E-mail: *bhansen@wlgore.com*

Performance Standardssmmary

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The GORE BIOABSORBABLE MESH is used to reinforce soft tissue during the phases of wound healing by filling or bridging soft-tissue void spaces or defects. The GORE BIOABSORBABLE MESH elicits a physiological tissue response, which fills the defect with native tissue and gradually absorbs the device.

GORE® BIOABSORBABLE MESH is comprised of a microporous structure of synthetic bioabsorbable poly (67% glycolide: 33% trimethylene carbonate by weight) (PGA: TMC) copolymer fiber. This is the same material used in the predicate device (GORE DRAPEABLE ST Regenerative Membrane, K013346, cleared December 19, 2001 and SEAMGUARD, K030782 cleared April 21, 2003).

As packaged, the GORE BIOABSORBABLE MESH is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the absorptive nature of the device stimulates the body to fill the defect with native tissue. The device is available in sheets and preformed, three-dimensional shapes. The GORE BIOABSORBABLE MESH is provided STERILE for single use only.

Due to the absorptive nature of the GORE BIOABSORBABLE MESH, an overlay patch should be used in corrections requiring high strength (e.g., groin hernia repair)

Indication for Use

The GORE BIOABSORBABLE MESH is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIOABSORBABLE MESH may be used include, but are not limited to:

Hernia repair (inguinal, femoral, umbilical, abdominal, diaphragmatic, incisional, epigastric, gastroesophageal, hiatal, intermuscular).

Colon, rectal, urethral, and vaginal prolapse

Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.)

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Substantially Equivalent Devices

In W. L. Gore & Associates, Inc.'s opinion, the GORE BIOABSORBABLE MESH is believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- SEAMGUARD Bioabsorbable Staple Line Reinforcement Material (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K030782
- GORE DRAPEABLE ST Regenerative Membrane (W. L. Gore & Associates, Inc., Flagstaff, AZ) – K013346
- Vicryl (Ethicon Inc., Somerville, NJ) – K810428
- DePuy Restore® Orthobiologic Soft Tissue Implant (DePuy, Inc., Warsaw, IN) – K001738
- FortaGen (Organogenesis Inc., Canton, MA) – K021105

Summary of Studies

W. L. Gore & Associates, Inc. performed device integrity testing to support that the GORE BIOABSORBABLE MESH is equivalent to the predicate devices. All device integrity test results for the GORE BIOABSORBABLE MESH met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the W. L. Gore & Associates, Inc. GORE BIOABSORBABLE MESH through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 1 2003

Mr. Brandon Hansen
Regulatory Affairs
Medical Products Division
W.L. Gore & Associates, Inc.
3450 West Kiltie lane
Flagstaff, Arizona 86002-0500

Re: K033671
Trade/Device Name: Gore Bioabsorbable Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: November 21, 2003
Received: November 24, 2003

Dear Mr. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033671

INDICATION FOR USE

510(k) Number (if known): _____

Device Name: GORE BIOABSORBABLE MESH

Intended Use / Indication For Use:

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Muscle flap reinforcement

Perforated tissue repair

General tissue reconstruction's (pelvic floor, periosteum, thoracic wall, bladder, suture line reinforcement, tissue deficit, etc.).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033671